

Encorafenib (Braftovi), Cetuximab (Erbix), and FOLFOX (Leucovorin, Fluorouracil (5-FU), Oxaliplatin)

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for cancer of the colon or rectum (colorectal cancer), but it may also be used for other uses.
- Your care team will perform a test for a certain “BRAF” gene to make sure that treatment is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

- The targeted therapy parts of your treatment are encorafenib and cetuximab.
- The chemotherapy part of your treatment is often called by its acronym: FOLFOX (pronounced "FOI-foks").
 - **FOL:** Leucovorin (**F**olinic Acid)
 - **F:** Fluorouracil
 - **OX:** Oxaliplatin

Treatment Name	How the Treatment Works	How the Treatment is Given
Encorafenib (EN-kor-A-feh-nib): Braftovi (braf-TOH-vee)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Capsules taken by mouth.
Cetuximab (seh-TUK-sih-mab): Erbix (ER-bih-tux)	Slows down or stops cancer growth by blocking a specific protein that cancer cells need to survive.	Infusion given into a vein.
Leucovorin (LOO-koh-VOR-in)	Helps fluorouracil (5-FU) bind more tightly to its target inside cancer cells. This allows it to stay and fight longer.	Infusion given into a vein.
Fluorouracil (floor-oh-YOOR-uh-sil) It is also called “5-FU”.	Stops cancer cells from making the instructions they need to grow and multiply, causing the cells to die.	Infusion given into a vein. It is often given in two parts: first, a quick, concentrated dose (called a "bolus"), followed by a continuous infusion through a pump over 2 days (46-48 hours).
Oxaliplatin (ok-SA-lih-pla-tin): Eloxatin (eh-LOK-sah-tin)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply.	Infusion given into a vein.

Treatment Administration and Schedule: Cetuximab and FOLFOX are typically repeated every 2 weeks. This length of time is called a “cycle.” Encorafenib is taken by mouth 1 time each day.

- The continuous infusion of fluorouracil (5-FU) is given over 2 days (46-48 hours), ending on Day 3.
- Sometimes your care team will remove the leucovorin, the bolus dose of fluorouracil (5-FU), or both from your treatment plan. Talk with your care team about the exact treatments you will receive.

Treatment Name	Cycle 1														Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 1
Treatment Given at the Hospital or Clinic															
Cetuximab	✓														✓
Leucovorin	✓														✓
Oxaliplatin	✓														✓
Fluorouracil (5-FU) Bolus	✓														✓
Fluorouracil (5-FU) Continuous Infusion	→	→	→												→
Treatment Taken at Home															
Encorafenib	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Your encorafenib dosing instructions:

- Encorafenib comes in 1 capsule strength: 75 mg.
- Your dose may differ, but encorafenib is typically taken as 300 mg (four 75 mg capsules) by mouth once daily.
- Take encorafenib by mouth 1 time each day, around the same time each day.
- Encorafenib may be taken with or without food.
- Swallow encorafenib capsules whole with water. Do NOT open, crush, or break your capsules. If you cannot swallow the capsules whole, tell your care team.
- If you miss a dose of encorafenib, take it as soon as you remember. If it is within 12 hours of your next scheduled dose, take your next dose at your regular time. Do not make up for the missed dose.
- Do not take an extra dose if you vomit after taking your scheduled dose. Take your next dose at your regular time.
- If you stop treatment with cetuximab, talk to your care team about your encorafenib treatment. Your encorafenib dose may need to be changed or stopped.

Storage and Handling of Encorafenib

- Store encorafenib at room temperature between 68°F to 77°F (20°C to 25°C).
- Store encorafenib in the original bottle.
- Keep the encorafenib bottle tightly closed and protect it from moisture.
- Encorafenib comes with a desiccant packet in the bottle to help protect your medicine from moisture. Do not remove the desiccant packet from the bottle.
- Keep encorafenib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused encorafenib.

Appointments: Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent infusion-related reactions		
To help prevent or treat nausea and vomiting		
To help prevent an acne-like rash		
Other		

Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count and Increased Risk of Infection	<p>Description: WBCs help protect the body against infections. If you have a low WBC count, you may be at a higher risk of infection.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Wash your hands and bathe regularly. • Avoid crowded places. • Stay away from people who are sick. • Your care team may prescribe a drug that promotes the growth of WBCs. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Fever of 100.4 °F (38°C) or higher • Chills • Cough • Sore throat • Painful urination • Tiredness that is worse than normal • Skin infections (red, swollen, or painful areas)
Low Platelet Count	<p>Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you are at a higher risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medications that may increase the risk of bleeding, such as NSAIDs. • Talk with your care team or dentist before medical or dental procedures, as you may need to pause your treatment. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Nosebleed lasting over 5 minutes despite pressure • Cut that continues to bleed • Significant gum bleeding when flossing or brushing • Severe headaches • Blood in your urine or stool • Blood in your spit after a cough
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb)	<p>Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you may feel weak, tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Get 7 to 8 hours of sleep each night. • Avoid operating heavy machinery when tired. • Balance work and rest, staying active but resting when needed. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Fast or abnormal heartbeats • Severe headache

Fatigue	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you. • Ask your family and friends for help with daily tasks and emotional support. • Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good. • Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep. • Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Tiredness that affects your daily life • Tiredness all the time, and it doesn't get better with rest • Dizziness and weakness, along with being tired
Nausea and Vomiting	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food. • Your care provider may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Vomiting for more than 24 hours • Vomiting that's nonstop • Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine) • Blood or coffee-ground-like appearance in your vomit • Bad stomach pain that doesn't go away after vomiting
Mouth Irritation and Sores	<p>This treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Rinse your mouth after meals and at bedtime, and more often if sores develop. • Brush your teeth with a soft toothbrush or cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least four times daily (after meals and at bedtime). A simple mixture is 1/8 teaspoon salt and 1/4 teaspoon baking soda in 8 ounces of warm water. • Avoid acidic, hot, spicy, or rough foods and drinks that may irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwashes. • Your care team may prescribe medicine for these symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Pain or sores in your mouth or throat

<p>Decreased Appetite</p>	<p>Description: Treatment can cause a low appetite, which means you may not feel like eating much. It's important to eat enough so your body gets the nutrients it needs to heal and stay strong. Eating healthy foods helps you feel better and recover faster.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Be as active as possible. Do some physical activity before a meal. Before starting an exercise program, talk with your care team. • Take note of the times during the day when your appetite is best. Do not limit food when your appetite is good. Eat your largest meal when you feel the most hungry, whether it is breakfast, lunch, or dinner. • Eat 5-6 small meals per day and snack anytime. • Choose foods high in protein, such as beans, chicken, fish, meat, yogurt, tofu, and eggs. During meals, eat high-protein foods first. • Choose foods that are high in calories. Do not select foods that are labeled "low-fat," "fat-free" or "diet." • If you feel full quickly when eating, do not drink any liquids 30 minutes before a meal so you have more room for solid food. Then, drink liquids between meals. Choose liquids with extra calories, not diet drinks. • Eat a bedtime snack. Choose something easy to digest, such as peanut butter and crackers. If you tend to experience reflux or heartburn, eat at least an hour before lying down. • If food is not appealing, try a nutritious beverage, such as a high-protein shake or smoothie, instead of solid food. • Ask your care team to recommend a liquid nutrition supplement. Add a scoop of protein powder, yogurt, or ice cream for added protein and calories. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Weight loss • No appetite • Tiredness
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Diarrhea	<p>Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep track of how many times you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids every day, unless your doctor tells you otherwise. • Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast. • Stay away from foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods. • Your care team may recommend a medicine (such as loperamide) for diarrhea. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Bloody diarrhea
Sensitivity to Cold Temperatures	<p>Description: Oxaliplatin can make you sensitive to the cold for 3-7 days after treatment. You may feel discomfort or pain in your hands, feet, or other areas when exposed to cold weather or cold objects. It can be challenging to stay warm or handle cold items, such as ice or cold drinks. Some patients notice this sensitivity right after treatment or in cold environments.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Avoid cold temperatures and cold objects • Avoid cold drinks, ice, and cold food • Use a straw for cold liquids. • Wear gloves when reaching into the freezer or handling anything cold. • Dress warmly in cold weather, using gloves and a scarf to cover your mouth. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Severe or persistent pain when exposed to cold temperatures. • Numbness or tingling that worsens or spreads to other areas. • Difficulty performing daily activities due to cold sensitivity. • Any unusual symptoms, such as skin discoloration or sores, in response to cold. • If your cold sensitivity lasts longer than 7 days after treatment.

<p>Nerve Problems in Your Arms, Hands, Legs, Feet, or Jaw</p>	<p>Description: Nerve pain and tingling are uncomfortable sensations caused by nerve damage or irritation. Pain may be sharp, burning, or deep, while tingling feels like pins-and-needles or mild electric shocks, often in the hands, feet, arms, legs, or jaw.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Track your pain levels, sensations, and any triggers or factors that make the pain worse or better. • Check your feet daily for any injuries or changes, especially if you have numbness or tingling that affects your feeling. • Your care team may prescribe or recommend medicine for symptoms. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • “Pins and needles” or burning feeling in your hands or feet • Trouble moving your arms or legs • Trouble keeping your balance
<p>Acne-like Rash</p>	<p>Description: An acne-like rash is a skin condition. It usually appears on the face, neck, and back, causing red, inflamed bumps that may itch or feel dry.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Your care team may prescribe medicine for rash. • If you get a rash, keep the area clean and dry. • Check with your care team before using any treatments. • Do not use over-the-counter acne treatments like benzoyl peroxide or salicylic acid, or soaps with alcohol. • Wash with a mild, moisturizing soap, and avoid long, hot baths or showers. • After washing, pat your skin dry instead of rubbing. • Oatmeal baths and unscented moisturizers may relieve itching. • Sunlight can worsen symptoms, so avoid sun exposure whenever possible. • Wear long-sleeved clothing with UV protection if possible. • Use broad-brimmed hats for added protection. • Apply broad-spectrum sunscreen (UVA/UVB, at least SPF 30) as directed. • Use lip balm with at least SPF 30. • Avoid tanning beds. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful or worsening rash • Rash that does not improve with treatment

<p>Rash, redness, swelling, itching, or peeling of your skin on your hands and feet (Hand-Foot Syndrome)</p>	<p>Description: Hand-Foot Syndrome causes dryness, thickening, swelling, or blisters of the skin on the palms of your hands and soles of your feet.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Keep hands and feet moisturized with a non-scented moisturizing cream. • Applying urea 10% or 20% cream twice daily to the affected area may be helpful. • Avoid exposure to hot water on the hands and feet in showers or baths that may dry out the skin or by doing dishes. • Avoid tight-fitting shoes or socks. • Avoid excess rubbing on hands and feet unless putting on lotion. • Wear gloves when working with your hands. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Painful blisters or calluses
<p>Decreased Levels of Magnesium in the Blood</p>	<p>Description: Treatment can cause low levels of blood magnesium. Your care team will do blood tests to check your magnesium levels before and during treatment.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> • Your care team may recommend or prescribe medicine to treat low magnesium. <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> • Irregular heartbeat • Muscle spasms, twitching, cramps, or weakness • Extreme tiredness • Abnormal eye movements • Confusion • Seizures

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Infusion Reactions (Cetuximab Boxed Warning)	<ul style="list-style-type: none"> Chills or shaking Itching, rash, or flushing Trouble breathing or wheezing; tongue-swelling Dizziness or feeling faint Fever of 100.4°F (38°C) or higher Pain in your back or neck 	
Severe Allergic Reactions (Oxaliplatin Boxed Warning)	<p>Get emergency help right away if you develop any of the following signs or symptoms:</p> <ul style="list-style-type: none"> Swelling of your lips, mouth, tongue, or throat Trouble breathing or swallowing Raised red areas on your skin (hives) Very fast heartbeats Dizziness or fainting 	
Heart Problems	<ul style="list-style-type: none"> Swelling of your stomach-area (abdomen), legs, hands, feet, or ankles Shortness of breath Nausea or vomiting Weight gain Pain or discomfort in your arms, back, neck, or jaw Protruding neck veins 	<ul style="list-style-type: none"> Palpitations (rapid or irregular heartbeat) Dizziness or lightheadedness Chest discomfort or pain Fatigue Confusion Fainting or near-fainting spells Breaking out in a cold sweat
Liver Problems	<ul style="list-style-type: none"> Yellowing of your skin or the whites of your eyes Severe nausea or vomiting Pain on the right side of your stomach area (abdomen) 	<ul style="list-style-type: none"> Dark urine (tea colored) Bleeding or bruising more easily than normal
Eye Problems	<ul style="list-style-type: none"> Dry or red eyes Eye pain or swelling Vision changes 	<ul style="list-style-type: none"> Increased tears Sensitivity to light Blurred vision
Lung Problems	<ul style="list-style-type: none"> Cough Shortness of breath 	<ul style="list-style-type: none"> Chest pain
Risk of New Cancers	<p>Encorafenib may cause skin cancers, such as cutaneous squamous cell carcinoma (cuSCC), keratoacanthoma, basal cell carcinoma, or melanoma. Your care team may check your skin before treatment, during treatment, and after you stop taking encorafenib to look for any new skin cancers.</p> <p>Check your skin and tell your healthcare provider right away about any skin changes, including a:</p> <ul style="list-style-type: none"> New wart Skin sore or reddish bump that bleeds or does not heal Change in size or color of a mole 	

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
 - If you might get pregnant, take a pregnancy test before starting treatment.
 - Use an effective method of birth control during treatment, 2 months after your last dose of cetuximab, and 9 months after your last dose of oxaliplatin.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner(s) could be pregnant, use an effective method of birth control—such as condoms—during treatment and for 6 months after your last dose of oxaliplatin.
- **Do NOT breastfeed**
 - during treatment.
 - 2 weeks after your last dose of encorafenib.
 - 2 months after your last dose of cetuximab.
 - 3 months after your last dose of oxaliplatin.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **6 days** after each dose of **oxaliplatin** and **48 hours** after each dose of **fluorouracil (5-FU)**.

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

Additional Information

- **Tell your care team about all the medicines you take.**
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Do not drink grapefruit juice or eat grapefruit.** Grapefruit may increase the amount of encorafenib in your blood.
- **People with deficiencies in the enzyme dihydropyrimidine dehydrogenase (DPD) may experience serious side effects.**
People with certain changes in a gene called "DPYD" may have a deficiency of the DPD enzyme. Some of these people may not produce enough DPD enzyme, and some of these people may not produce the DPD enzyme at all.
 - People who do not produce any DPD enzyme are at increased risk of sudden side effects that come on early during treatment with fluorouracil (5-FU) and can be serious, and sometimes lead to death.
 - Call your care team right away if you develop any of the following symptoms and they are severe, including:
 - Sores of the mouth, tongue, throat, and esophagus
 - Diarrhea
 - Low white blood cell counts
 - Nervous system problems
 - People with some DPD enzyme may have an increased risk of serious side effects with fluorouracil (5-FU) treatment that can sometimes lead to death.
 - Your care teams should talk with you about DPYD testing to look for DPD deficiency.
- **People with galactose- α -1,3-galactose (alpha-gal) IgE antibodies may have an increased risk of anaphylactic reactions.** Your care team may consider testing for alpha-gal IgE antibodies before your start treatment. However, severe infusion reactions may still happen with a negative result.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

Updated Date: January 12, 2026

Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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